DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 17-111/SLR-055
NDA 17-938/SLR-022

Endo Pharmaceuticals, Inc.
Attention: Ira Lentz
Manager, Regulatory Affairs, Labeling
223 Wilmington West Chester Pike
Chadds Ford, PA 19317

Dear Mr. Lentz:

Please refer to your supplemental new drug applications dated December 13, 2000, received December 14, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Moban (molindone HCl) tablets and concentrate.

These "Changes Being Effected" supplemental new drug applications provide for the labeling changes requested in our letter of September 25, 2000, specifically modification of labeling text to more clearly state that these agents are indicated for the treatment of schizophrenia.

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the package insert (final printed labeling) submitted December 13, 2000. Accordingly, these supplemental applications are approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Steven D. Hardeman, R.Ph., Senior Regulatory Project Manager, at (301) 594-5525.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research